

OCT 15 1996

Summary of Safety and Effectiveness

As required by 21 CFR 807.92, the following 510(k) Summary is provided:

1. Submitters Information

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2. Device Information

Proprietary Name: Ciba Corning ACS:180 DPD Assay
Common Name: Assay for Deoxypyridinoline

3. Predicate Device Information

Name: Pyrilinks®-D
Manufacturer: Metra Biosystems, Inc

4. Device Description

The Ciba Corning ACS:180 DPD assay is a competitive immunoassay using direct, competitive chemiluminescent technology. DPD in the patient sample competes with pyridinoline bound to the paramagnetic particles in the Solid Phase for a limited amount of monoclonal mouse anti-DPD antibody in the Lite Reagent. The monoclonal mouse anti-DPD is bound to goat anti-mouse antibody labeled with acridinium ester. An inverse relationship exists between the amount of DPD present in the sample and the amount of relative light units (RLUs) detected by the system.

5. Statement of Intended Use

The intended use of Ciba Corning Ciba Corning ACS:180 DPD Assay is for the quantitative of deoxypyridinoline (DPD) in urine using the Ciba Corning ACS:180 automated chemiluminescence systems

6. Summary of Technological Characteristics

The Ciba Corning ACS:180 DPD assay is a competitive immunoassay using direct, competitive chemiluminescent technology

7. Performance Characteristics

Sensitivity

The ACS:180 DPD assay measures DPD concentrations up to 350 nM with a minimum detectable concentration of 5.0 nM. Analytical sensitivity is defined as the concentration of DPD that corresponds to the RLUs that are two standard deviations less than the mean RLUs of 20 replicate determinations of the DPD zero standard.

Method Comparision

For 752 urine samples in the range of 6 to 350 nM, the relationship between ACS:180 DPD and an alternate ELISA method is described by the equation:

ACS:180 DPD = 1.05 (alternate method)+2.13

Correlation coefficient (r) = 0.961

Precision

Total precision (%CV) ranged from 2.84 to 9.76